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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/870,376   | 05/30/2001  | Jeffrey P. Bodner    | 279.368US1          | 7232             |
| 21186  | 7590        | 12/15/2005           | EXAMINER            |                  |
| SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH<br>1600 TCF TOWER<br>121 SOUTH EIGHT STREET<br>MINNEAPOLIS, MN 55402 |             |                      | OROPEZA, FRANCES P  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3766                |                  |

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/870,376

Applicant(s)

BODNER, JEFFREY P.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/26/05 (Amendment and Response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/9/04, 12/13/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Applicant's Comments***

1. The Applicant's arguments filed 9/26/05 have been fully considered and are convincing, hence the rejection of record with withdrawn and a new rejection established in the subsequent paragraphs.

### ***Claim Rejections - 35 USC § 102***

2. Claims 1-7, 9-13, 15-20, 22, 24-26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Cobain et al. (US 5796044). Cobain et al. teach a lead assembly with two co-axial and non co-radial single filar or multi-filar conductors. The second conductor is disposed within the first conductor, and the first and second second conductors may have an insulative coating surrounding the outer filar surface such that a cross-section of the outer filar surface is surrounded by an insulative coating (abstract; col. 5 @ 12-60). All leads have a flexibility, the disclosed lead has flexibility enabling placement in the heart (col. 8 @ 1-6).

As to claims 3, 4, 6, 13 and 17, an insulative sleeve (38)/ tube/ redundant insulation is disposed between the first and second conductor (fig. 9; col. 11 @4-6). The internal sheath (27) is noted to be optional (col. 8 @ 44-47).

As to claims 5, 10, 15, 16, 22 and 26, the sleeve/ coating can be made of a non-silicon polymer such as polyurethane, ETFE, PTFE, and PFA (col. 5 @ 57-67; col. 12 @ 42-50).

As to claims 9, 13, 17, 20, 28 and 29, the first conductor is insulated (22) (fig. 9; col. 11 @ 4-9).

As to claims 11, 18 and, 25, an extendable/ retractable electrode is taught (col. 8 @ 1-14).

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3. Claims 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobain et al. (US 5796044) in view of Helland et al. (US 5545201). As discussed in paragraph 2 of this action, Cobain et al. disclose the claimed invention except for a means for facilitating rotation of the second conductor relative to the first conductor.

Helland et al. teach an electrode configuration using an electrode assembly with an extendable/ retractable electrode (144) coupled to the second conductor, the electrode rotated by the means for facilitating rotation/ conductive plug (176) for the purpose of fixing/ securing the electrode to the heart wall. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an extendable/ retractable electrode coupled to the second conductor, the electrode rotated by the means for facilitating rotation/ conductive plug in the Cobain et al. system in order to accurately sense and stimulate the heart so there is accurate discrimination of the cardiac rhythm enabling effective therapy to be offered to the patient (figure 6; col. 1 @ 6-11 and 48-58; col. 1 @ 62 – col. 2 @ 5; col. 4 @ 56 – col. 5 @ 15).

4. Claim 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobain et al. (US 5796044) in view of Altman et al. (US 5845396). As discussed in paragraphs 2 of this action, Cobain et al. disclose the claimed invention except for the insulation being a polyimide material.

Altman et al. teach signal conduction using a lead with polyimide coated conductors for the purpose of isolating the conductors so noise and artifacts do not degrade the quality of the electrical signals. It would be an obvious design choice to fashion the insulation by substituting one known lead insulating material for another as a mere substitution of known functional

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equivalents in order to effectively insulate the conductors so electrical signals associated with the heart can be accurately sensed and delivered (col. 1 @ 6-10; col. 2 @ 34-36).

5. Claims 23, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobain et al. (US 5796044) in view of Nelson et al. (US 6249708). As discussed in paragraph 2 of this action, Cobain et al. teach applying various Teflon™ materials such as PTFE and ETFE on the second outer coil diameter and over the insulation (col. 5 @ 57-67; col. 12 @ 42-50), but do not teach applying heat shrunk Teflon™ material on the second outer coil diameter and insulation (claims 23 and 27).

Nelson et al. teach lead construction using heat-shrunk Teflon™ (38) for the purpose of insulating the central core conductor (34). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a heat-shrunk Teflon™ PTFE or ETFE to on the second outer coil diameter and insulation in the Cobain et al. system in order to reinforce the assembly and provide a proven alternate approach of applying Teflon™ to the second outer coil diameter and insulation, hence adding flexibility in the lead manufacturing process (col. 4 @ 27-45; col. 7 @ 46-48).

#### ***Statutory Basis***


6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza  
Patent Examiner  
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FP  
12/8/05

  
Robert E. Pezzuto  
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